510(k) Summary

K053550

1. 510(k) owner:
Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark
Tel.: +45 72252000
Fax.: +45 72252050

OCT 25 2006

Contact person:
Laila Strange Lundtoft
Regulatory Affairs Manager

2. Preparation date of the 510(k) summary: 8. December 2005

3. Name of device:

Device Common name:	Disposable ECG electrode
Device Trade name:	Ambu® Blue Sensor NEO Ambu® Blue Sensor NEO X
Classification Name:	Electrode, Electrocardiograph. 21 CFR 870.2360
Product Code:	DRX

4. Identifies the legally marketed device to which equivalence is claimed

Manufacturer	Trade Name	Product code
Ambu A/S	Ambu® Blue Sensor NF	DRX
Ambu A/S	Ambu® Blue Sensor BRS	DRX

~~E-1~~

5. Description of device
   Ambu® Blue Sensor NEO/NEO X is non-sterile, self-adhesive ECG electrodes. Ambu® Blue Sensor NEO/NEO X should only be used by or on the order of a physician.
   Ambu® Blue Sensor NEO/NEO X is single patient use disposable devices.

   Ambu® Blue Sensor NEO/NEO X is a multi-layer construction containing a pre-attached lead wire with an attached connector, a top disc, a top film, a sensor and a hydrogel adhesive.

6. The intended use
   Ambu® Blue Sensor NEO/NEO X is for ECG monitoring of Neonatal and Paediatric care.

7. Summary of the technological Characteristics
   The technological characteristics of Ambu® Blue Sensor NEO/NEO X are identical to the predicate devices.
   Ambu® Blue Sensor NEO/NEO X is a multi-layer construction containing a pre-attached lead wire with an attached connector, a top disc, a top film, a sensor and a hydrogel adhesive.

8. Brief discussion of the nonclinical tests submitted
   The non-clinical tests performed are laboratory tests to ensure the electrical and mechanical functionality of the electrode meets the standard ANSI/AAMI EC12:2000 – Disposable ECG Electrodes.

9. Brief discussion of the clinical tests submitted
   No clinical tests are performed

10. Biocompatibility testing
    The biological safety of the Ambu® Blue Sensor NEO/NEO X has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Tests were selected on the basis of ISO 10993-1 – Biological evaluation of Medical Devices.

11. Conclusions drawn from the nonclinical, clinical and biocompatibility tests
    Aging test of Ambu® Blue Sensor NEO/NEO X and comparison test to predicate devices have been performed. From the results it has been concluded that the Ambu® Blue Sensor NEO/NEO X have equivalent electrical and mechanical functionality as the predicate devices.
    The Ambu® Blue Sensor NEO/NEO X meet the mandatory performance standard requirements under ANSI/AAMI EC12:2000 – Disposable ECG electrodes.
    The biocompatibility of the Ambu® Blue Sensor NEO/NEO X have been established.
    It is concluded that Ambu® Blue Sensor NEO/NEO X are safe and effective electrodes and comparable to the predicate devices.

~~E-2~~

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2006

Ambu Inc.
c/o Mr. Sanjay Parikh
Technical and Regulatory Affairs
6740 Baymeadow Dr.
Glen Burnie, MD 21060

Re: K053550
Trade Name: Ambu® Blue Sensor NEO & Ambu® Blue Sensor NEO-X
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: October 10, 2006
Received: October 12, 2006

Dear Mr. Parikh:

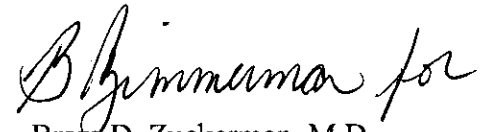
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053550

Device Name: **Ambu® Blue Sensor NEO and Ambu® Blue Sensor NEO X**

Indications For Use:

The Ambu® Blue Sensor NEO and Ambu® Blue Sensor NEO X electrodes are made for ECG monitoring of neonatal and paediatric patients. The ECG electrodes are applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. The electrodes are for single patient use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053550